

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in light of the following remarks and pursuant to 37 C.F.R. § 1.116, are respectfully requested.

Claims 1-29, 81-133, and 136-138 are currently pending; claims 30-80 and 134-135 are cancelled.

By the present amendment, the claims have been amended to correct minor errors (claims 81 and 108), recite proper Markush groups (claims 84 and 116), and to recite in claim 124 that the transcriptional initiation region is specifically regulated in embryonic seed tissue. No new matter enters by this amendment.

Applicants would like to thank the Examiner for his indication that claims 1-18, 131 and 132 are free of the prior art.

Rejections Under 35 U.S.C. § 251

Claims 19-29, 81-130, 133 and 136-138 have been rejected under 35 U.S.C. § 251 for allegedly being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. For at least the reasons set forth below, withdrawal of this rejection is believed to be in order.

Initially, Applicants would like to thank the Examiner for his indication that claims 131 and 132 are no longer subjected to a rejection under 35 U.S.C. § 251.

As noted previously, pending claims 19-20 are directed to plant parts having an altered phenotype as a result of transcription of a DNA construct comprising, amongst other components, a promoter region obtainable from a gene that is preferentially regulated in embryonic seed tissue. Pending claims 21-24 are directed to DNA constructs comprising, amongst other components, a promoter region obtainable from a gene that is preferentially regulated in embryonic seed tissue. Claims 25-29 are directed to plant cells and plants comprising a DNA construct comprising, amongst other components, a promoter region

obtainable from a gene that is preferentially regulated in embryonic seed tissue. Claims 81-130 and 136-138 are directed to methods for obtaining a plant having a regulatable phenotype; methods for altering the phenotype of a plant tissue of interest; methods for modifying the genotype of a plant to impart a desired characteristic to a plant tissue of interest; methods for modifying transcription in plant tissue of interest; and methods of selectively expressing a heterologous DNA sequence of interest in a plant tissue of interest, comprising transforming a plant cell with a DNA construct comprising, amongst other components, a promoter region obtainable from a gene that is preferentially regulated in embryonic seed tissue.

The Examiner purports that claims 107-108 in the parent application were directed to the same subject matter. Claims 107 and 108 recite that the gene “is transcribed during seed embryogenesis.” In an Official Action mailed on August 29, 1996, in the parent application, these claims were rejected under 35 U.S.C. § 103 for purportedly being unpatentable over Hall *et al.* taken with Sengupta-Gopalan *et al.* The limitation “is transcribed during seed embryogenesis” in claims 107 and 108 is much broader than the limitation “preferentially regulated in embryonic seed tissue” in the pending claims, as the gene, for example, could be preferentially regulated in another plant part during another stage of development. Therefore, these claims are narrower than the claims cancelled in U.S. Appl. Ser. No. 08/105,852. As noted in *In re Clement*, 131 F.3d, 1464, 1470, 45 USPQ2d 1161, 1165 (Fed. Cir. 1997), “...if the reissue claim is narrower in an aspect germane to [a] prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim...” With respect to the above claims, there is no recapture since the claims are narrower in an aspect germane to a rejection of the claims in the parent application.

Claim 133 is directed to a method for altering the phenotype of a dicotyledonous plant tissue of interest comprising growing a dicotyledonous plant comprising cells containing a DNA construct comprising, amongst other components, a promoter region obtainable from a gene that is light inducible in plant chloroplast containing tissue. The Examiner purports that claims of a similar scope were presented in the parent application, and cancelled in response to a prior art rejection. The Examiner also purports that the limitation “dicotyledonous” was not germane to

the prior art rejection in the parent application. However, Applicants note that the Examiner has not rejected pending claim 133 for being anticipated or obvious in view of the art cited against those claims of purportedly similar scope in the parent application. Specifically, claim 101 of the parent application was rejected under 35 U.S.C. § 102(e) for purportedly being anticipated by Rogers *et al.* Rogers *et al.* has not been cited against any of the claims in the pending application. Claim 101 of the parent application was also rejected under 35 U.S.C. § 103 for being obvious over Zambryski *et al.* taken with Pedersen *et al.*, Rogers *et al.*, and Borglie *et al.* This rejection has also not been raised against currently pending claim 133. In light of this, recapture does not exist.

Double Patenting Rejections

Applicants reaffirm their intent to file terminal disclaimers in response to each of the double patenting rejections upon indication of allowable subject matter.

Rejection of Claims 19-29, 81-130, 133 and 136-138 Under 35 U.S.C. § 112, First Paragraph

Claims 19-29, 81-130, 133 and 136-138 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly not being enabled by the specification as filed for the use of DNA constructs comprising any seed specific promoter. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Initially, Applicants would like to thank the Examiner for his indication that the specification does enable claims directed to the use of seed specific promoters from *Brassica*, and for light-inducible/chloroplast containing tissue specific or fruit specific promoters and methods for their use. Moreover, “it is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art.” *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991); *Application of Angstadt*, 537 F.2d 498, 503 (CCPA 1976). This is emphasized in *In re Hogan*, 559 F.2d 595 (CCPA 1977). In *Hogan*, the court found that the phrase “a solid polymer” in the claims included a crystalline form (specifically disclosed in

the specification) and an amorphous form (which did not exist until almost nine years after filing of the first filed application). The court stated “[t]o restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restrictions is merely to state a policy against broad protection for pioneer inventions...” *Id.* at 606.

The Federal Circuit expanded on *Hogan* in *Plant Genetic Systems, N.V. v. Dekalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003), when it stated “[w]e do not read *Hogan* as allowing an inventor to claim what was specifically desired but difficult to obtain at the time the application was filed, unless the patent discloses how to make and use it.” *Id.* at 1340 (emphasis added). In the patent for which reissue is sought, Applicants do disclose how to isolate promoters from genes preferentially expressed in seed tissue, and how to use these seed-specific promoters in the constructs of the invention. See, for example, column 8, lines 10-18 (wherein transcription initiation regions for various genes preferentially expressed in embryonic seed tissue are disclosed); and column 30, line 63, to column 31, line 14 (wherein the identification of promoter regions from genes preferentially expressed in seed tissue is disclosed), of the patent for which reissue is sought.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 19-29, 81-130, 133 and 136-138 Under 35 U.S.C. § 112, First Paragraph

Claims 19-29, 81-130, 133 and 136-138 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter not described in the specification as filed in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner cites *University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997) as requiring a precise definition of the claimed subject matter, in this case a precise

definition of the promoter sequence. Applicants note that more recent Federal Circuit decisions have distinguished *Lilly*. See, for example, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), where the court found that one should determine what one of skill in the art would glean from the written description. See also *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), where the court cited *Enzo Biochem* as clarifying that:

Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

Id. at 1332.

In the patent for which reissue is sought, Applicants do disclose how to isolate promoters from genes preferentially expressed in embryonic seed tissue, and how to use these embryonic seed-specific promoters in the constructs of the invention. See, for example, column 8, lines 10-18 (wherein transcription initiation regions for various genes preferentially expressed in embryonic seed tissue are disclosed); and column 30, line 63, to column 31, line 14 (wherein the identification of promoter regions from genes preferentially expressed in seed tissue is disclosed), of the patent for which reissue is sought. The technologies used by the Applicants to identify regulatory regions and isolate promoters from genes preferentially expressed in embryonic seed tissue were disclosed in the parent application as filed.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims Under 35 U.S.C. § 102(e)

Claims 22, 24-27, 97-99, 101-102, 105, 107-109, 113-115, 117-118, 121, 123-125, 133 and 137 have been rejected under 35 U.S.C. § 102(e) for purportedly being anticipated by Hall *et al.* (U.S. Patent No. 5,504,200). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Hall *et al.* discusses a construct for seed-specific expression comprising the phaseolin gene and a promoter. In an Official Action mailed on July 15, 2003, in related U.S. Application Serial No. 09/782,130, the Examiner stated that Hall *et al.* does not teach a construct comprising a phaseolin promoter (or other seed specific promoter) and a heterologous gene (see page 13 of that Official Action). Therefore, Hall *et al.* could not possibly disclose a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in embryonic seed tissue; and a DNA sequence of interest, other than the native coding sequence of said gene.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(e).

Rejection of Claims 19-27, 81-130, 133 and 136-138 Under 35 U.S.C. § 103(a)

Claims 19-27, 81-130, 133 and 136-138 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Hall *et al.* taken with Sengupta-Gopalan *et al.* (*Proc. Natl. Acad. Sci* 82:3320-3324 (1985)). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Initially, Applicants have overcome the Enablement rejection (see above), and thus the claimed subject matter should be awarded the priority date of the parent application, which pre-dates the Sengupta-Gopalan *et al.* reference. Therefore, Sengupta-Gopalan *et al.* is not prior art to the present application.

Notwithstanding this, Hall *et al.* discusses a construct for seed-specific expression comprising the phaseolin gene and promoter. As noted above, in an Official Action mailed on July 15, 2003, in related U.S. Application Serial No. 09/782,130, the Examiner stated that Hall *et al.* does not teach a construct comprising a phaseolin promoter (or other seed specific promoter) and a heterologous gene (see page 13 of that Official Action). Therefore, Hall *et al.* could not possibly disclose a construct comprising, as operably linked components in the direction of

transcription, a promoter region obtainable from a gene preferentially regulated in embryonic seed tissue; and a DNA sequence of interest, other than the native coding sequence of said gene.

Sengupta-Gopalan *et al.*, even if taken in combination with Hall *et al.*, would not motivate one of the art to produce or lead one of the art to expect success in producing the constructs used in the methods of the claimed invention. Sengupta-Gopalan *et al.* discusses a construct comprising the phaseolin promoter and the phaseolin gene (or alternatively, the octopine synthase promoter and the phaseolin gene) (see page 3320, column 1, first paragraph). Sengupta-Gopalan *et al.* does not disclose or suggest a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in embryonic seed tissue; a DNA sequence of interest, other than the native coding sequence of said gene; and a transcription termination region. There was no expectation that the construct used in the methods of the claimed invention (and present in the plants and plant parts of the claimed invention) would be successful, as prior to the parent application being filed one of skill in the art would not have gleaned from these references that any promoter could be used to express genes heterologous to that promoter.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 28-29 Under 35 U.S.C. § 103(a)

Claims 28-29 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Hall *et al.* taken with Sengupta-Gopalan *et al.* and further in view of Zambryski *et al.* (*The EMBO J.* 2(12):2143-2150 (1983)) taken with Pederson *et al.* (*Plant Cell Reports* 2(4):201-204 (1983)). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

As discussed in more detail above, Hall *et al.* and Sengupta-Gopalan *et al.* do not disclose or even suggest the constructs of claims 21 and 22, or the plants of claims 26 and 27 (from which claims 28 and 29 depend). Specifically, even if the teachings of these references were taken

together, there would be no motivation to produce a construct in which the promoter is from a gene preferentially expressed in embryonic seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, and therefore they do not disclose or suggest plants comprising such constructs.

Zambryski *et al.* discloses a construct comprising promoter sequences from the Ti plasmid-specific nopaline synthase gene and coding sequences from nopaline synthase and a foreign gene contained in a pBR-like plasmid (see the paragraph bridging pages 2143 and 2144) and the transformation of tobacco, potato, carrot and petunia with such a construct. Zambryski *et al.*, in the paragraph bridging pages 2148 and 2149, discusses third-party references which purportedly disclose a vector comprising the nopaline synthase promoter and foreign coding sequences. However, Zambryski *et al.* does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in embryonic seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it suggest a plant comprising such a construct.

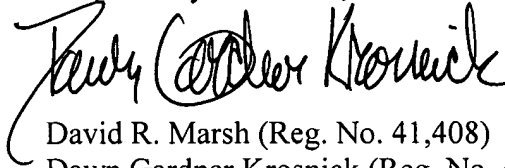
Pedersen *et al.* discusses the *Agrobacterium* mediated transformation of soybean plants. However, whatever else Pedersen *et al.* might discuss, it does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in embryonic seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it disclose plants comprising such constructs. Therefore, Pedersen *et al.* does not solve the deficiencies of Hall *et al.*, Zambryski *et al.* and Sengupta-Gopalan *et al.* because none of these references, even if taken together, would motivate one of skill in the art to produce or lead one of skill in the art to expect success in producing a construct in which the promoter is from a gene preferentially expressed in embryonic seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor do they disclose plants comprising such constructs. Therefore, Hall *et al.* in combination with Sengupta-Gopalan *et al.*, Zambryski *et al.*, and Pedersen *et al.* do not render unpatentable the claimed plants.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above, each of the presently pending claims in the application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is invited to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David R. Marsh", written over a horizontal line.

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